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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,782	07/03/2003	Patrizio Mattei	21159	6985
151	7590	12/29/2004	EXAMINER	
HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110			TRUONG, TAMTHOM NGO	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/613,782

Applicant(s)

MATTEI ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11, 12 and 14-18 is/are rejected.
- 7) ☒ Claim(s) 9, 10 and 13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/26/03 & 1/12/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-18 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-7, 11, 12 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. In claim 1, the definition of R^4 , the moieties of “heterocyclalkyl” and “heterocyclalkyl which is substituted” appear among substituents of “aryl”. However, dependent claims (e.g., claim 6) seems to recite “heterocyclalkyl”, “heterocyclalkyl which is substituted” as R^4 . Likewise, the moiety “cycloalkylalkyl” appears among substituents of “heterocyclalkyl” while dependent claims seems to recite “cycloalkylalkyl” as R^4 . Therefore, it is unclear if R^4 also represents “heterocyclalkyl” and “cycloalkylalkyl”, or if those rings are substituents on R^4 .

b. Claims 6 and 7 appear to be inconsistent with claim 1 with respect to the definitions of R^4 .

c. Claims 2-5, 11, 12 and 14-18 are rejected as being dependent on claim 1 and carrying over the limitation of R^4 .

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-4, 8, 11, 12, 14, 15 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by **Breu et. al.** (WO 02/20488 A2 – cited on IDS). On page 11, Breu et. al. list several quinazoline compounds, two of which (e.g. compounds on lines 13 and 14) read on compounds of the instant formula I with the following substituents:

- i. A is pyrrolidinyl or piperidinyl;
- ii. R^1 is $-N(R^5)(R^6)$ wherein R^5 and R^6 together with the N atom to which they are attached form a 6-membered heterocyclic ring such as *pyridine* and *pyrimidine*.
- iii. R^2 is an alkyl group (or methyl);
- iv. R^3 is hydrogen;

The disclosed compounds can also treat obesity, and the pharmaceutical composition for such a treatment is taught on page 24. Also, the disclosed compounds can be given with *orlistat* simultaneously, separately or sequentially. Therefore, the composition and method claims 14, 15, and 18 are also anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Breu et. al.** (WO'488). Said claims recite a "method of treatment of obesity...comprising administering....about 0.1 mg to 20 mg per kg body weight per day of the compound according to claim 1 and a therapeutically effective amount of from 60 to 720 mg per day of orlistat." As discussed in the rejection above, page 27 of WO'488 reveals that the disclosed quinazoline compounds can be administered with *orlistat*. The reference differs from the claims by not disclosing the dosage of *orlistat*. However, *orlistat* is a commercially available agent with an established dosage. Therefore, it would have been within the level of the skilled clinician to

administer the claimed compound with *orlistat* at a dosage recited in the instant claims 16 and 17. Thus, at the time of the invention, it would have been obvious to treat obesity according to the instant claims in view of the teaching of Breu et. al.

Claim Objections

4. Claims 9, 10 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 9 and 10 recite subgenera of formula (I) wherein R^1 is $-NR^5R^6$ with R^5 and R^6 as independent substituents, which is not taught or fairly suggested by Breu et. al. Similarly, claim 13 recites specific compounds of R^1 as OR^4 , or NR^5R^6 wherein R^4 , R^5 and R^6 are all independent substituents. Said compounds are not taught or fairly suggested by Breu et. al. either.

Reference cited on PTO-892


5. The reference cited on PTO-892 is a US corresponding of WO 92/07844 (cited on IDS). While said reference teaches related compounds, it does not teach a substituent equivalent to R^2 which is simply an amino. Thus, said reference does not anticipate or render obvious the instant formula (I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (10:00-6:30).

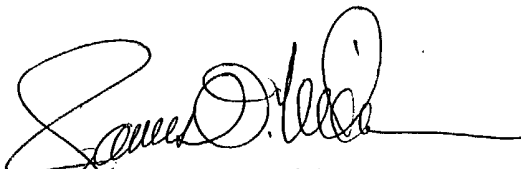
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Tamthom N. Truong
Examiner
Art Unit 1624

12-22-04


JAMES O. WILSON
EXAMINER
TECHNOLOGY CENTER 1000